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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,691	02/09/2001	Oliver Danne	81640	7836

7590 03/21/2003

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EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
1743	7

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	09/762,691	DANNE ET AL.
	Examiner	Art Unit
	Monique T. Cole	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 09 February 2001 .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recognizing and diagnosing acute myocardial infarction, does not reasonably provide enablement for all acute coronary syndromes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

3. Upon inspection of the instant specification, it appears that all correlations are directed towards CCTD and myocardial infarction. While Applicant does point out that levels of CCTD below the limit may be indicative of other coronary troubles, such a correlation does not appear to be absolute, as is the case with myocardial infarctions. In fact, it appears that more of a correlation is made between such coronary troubles as angina pectoris and troponin levels. At best, on page 22, the specification does seem to support instable angina pectoris along with myocardial infarction which may be diagnosed based on choline measurements. The instant claims, however, are directed to CCTD measurement and content and do not consider troponin levels. Thus, the instant claims do not seem to be commensurate in scope with instant disclosure. Further clarification and/or correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no correlation step set forth between the diagnosis of acute myocardial infarction and the content of choline, choline and/or trimethyl ammonium derivatives. A correlation step is necessary in the instant claims because without it one of ordinary skill would be unable to ascertain how the measurement of choline would have any relation to myocardial infarction. It is suggested the instant claims be amended to reflect that an increased level in CCTD is the cause of the myocardial infarction diagnosis. See page 4 & page 18 of the specification.

*Allowable Subject Matter*

6. Claims 1-11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first & second paragraph, set forth in this Office action.

7. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest using phosphoryl choline, plasmalogen or lysoplasmenyl choline or their derivatives as a marker for the diagnosis of myocardial infarction. The closest prior art does teach the relationship between lysophophatidyl choline and myocardial infarction, but does not conclusively teach the same relationship using lysoplasmenyl choline as the diagnostic marker.

*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

USP 5,747,274 teaches choline kinase among other diagnostic markers as being useful in the assessment of chest pain.

*"Calcim-independent phospholipase A<sub>2</sub> mediates CREB phosphorylation and c-fos expression during ischemia"* teaches that lysoplasmenylcholine plays a part in the cellular pathway that regulates myocardial ischemia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole  
Examiner  
Art Unit 1743

MC *MC*  
March 17, 2003

*Jill Warden*  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700